

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
 v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9172

Bartle, J.

December 4, 2013

Lucille A. Porter ("Ms. Porter" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Marion A. Porter, Ms. Porter's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust, he has signed at least 350 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram report dated October 31, 2001,⁴

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. The attesting physician relied on the report of claimant's echocardiogram because claimant was unable to obtain a copy of the echocardiogram tape. See Settlement Agreement § VI.C.2.f. The Trust did not contest that claimant had submitted the

(continued...)

Dr. Evans attested in Part II of Ms. Porter's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.⁵ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$490,388.⁶

In the report of claimant's echocardiogram, the reviewing cardiologist, Jeffery L. Curtis, M.D., F.A.C.C., F.A.C.P., stated that "the Doppler study shows an eccentric laterally directed jet of mitral insufficiency, at least moderate, perhaps moderately severe." Dr. Curtis, however, did not specify a percentage as to claimant's level of mitral regurgitation.⁷ Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is

4. (...continued)

affidavit required to rely on an echocardiogram no longer in existence.

5. Dr. Evans also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors necessary to qualify for a Level II claim.

7. Dr. Curtis also stated, "[Transesophageal echocardiogram] may be helpful in further delineating the morphologic abnormality of the mitral valve." On December 27, 2001, claimant underwent a transesophageal echocardiogram, which indicated that she had mild mitral regurgitation.

equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Curtis also noted that claimant had "moderate left atrial enlargement" with a left atrial dimension of 4.3 cm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii).

In June, 2008, the Trust forwarded the claim for review by Sui-Sun Yao, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Yao concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation based on the echocardiogram of attestation because claimant's December 27, 2001 echocardiogram demonstrated only mild mitral regurgitation and claimant's catheterization of the same date showed "no significant angiographic mitral insufficiency." Dr. Yao also determined that there was no reasonable medical basis for the attesting physician's finding that claimant had an abnormal left atrial dimension because the report of claimant's December 27, 2001 echocardiogram states that Ms. Porter's "left atrium size is normal."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Porter's claim. Pursuant to the Rules for the Audit of Matrix

Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁸ In contest, claimant argued that the issue is not whether her October 31, 2001 echocardiogram actually demonstrated moderate mitral regurgitation and an abnormal left atrial dimension but whether there was a reasonable medical basis for the attesting physician's representation to that effect. To support her argument, claimant relied upon an affidavit of the cardiologist who reviewed her October 31, 2001 echocardiogram, Dr. Curtis, wherein he stated: "This echocardiogram was interpreted by me in the ordinary course of my medical practice, and was ordered, performed and interpreted for the purpose of a medical diagnosis and treatment, and not for litigation." Claimant contended that the report of her October 31, 2001 echocardiogram and the affidavit of Dr. Curtis established a reasonable medical basis for her claim. Claimant further asserted that the Trust erred by considering the reports of her December 27, 2001 echocardiogram and catheterization because: (1) pursuant to § VI.C.4.b. of the Settlement Agreement, in the case of a missing echocardiogram tape, the Trust is permitted only to consider documents that support the claim; the Trust is not permitted to consider other documents that "do not tend to

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Porter's claim.

support the claim," and (2) pursuant to § VI.C.1.d. of the Settlement Agreement, a claimant cannot be disqualified from receiving Matrix payments based on a subsequent echocardiogram that does not reveal the presence of the required level of regurgitation or a necessary complicating factor if she previously qualified for Matrix payments based on "a properly interpreted Echocardiogram."

The Trust then issued a final post-audit determination, again denying Ms. Porter's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Porter's claim should be paid. On February 19, 2009, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8101 (Feb. 19, 2009).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 23, 2009. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review claims after the Trust and

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through (continued...)

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation and an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Porter repeats the arguments she made in contest. Claimant also contends that

9. (...continued)
the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Dr. Curtis was in a better position to evaluate whether Ms. Porter's October 31, 2001 echocardiogram qualifies her for Level II Matrix Benefits because he was her Board Certified treating physician with level 2 training in echocardiography and he actually reviewed the echocardiogram.

In response, the Trust argues that claimant did not adequately rebut Dr. Yao's findings at audit. Specifically, the Trust contends that the affidavit of Dr. Curtis does not provide a reasonable medical basis for Ms. Porter's claim because, in the echocardiogram report, he states that he observed a single jet of mitral insufficiency. According to the Trust, such an observation is insufficient to establish mitral regurgitation because a finding of mitral regurgitation may only be made after reviewing multiple loops and still frames. A single jet, the Trust states, "does not amount to a holosystolic jet that appears in consecutive frames and meets the 20% ratio required by the Settlement Agreement." The Trust also contends that it properly applied the Settlement Agreement because it may consider all medical records of a claimant rather than reviewing only documentation that supports payment of a claim for Matrix Benefits. Finally, the Trust asserts that claimant could not rely on § VI.C.1.d. of the Settlement agreement because the Trust determined she did not qualify for benefits based on the October 31, 2001 echocardiogram.

The Technical Advisor, Dr. Vigilante, reviewed claimant's December 27, 2001 echocardiogram and her

December 27, 2001 cardiac catheterization. As to claimant's December 27, 2001 echocardiogram, Dr. Vigilante concluded the following:

Visually, very mild mitral regurgitation was suggested in the appropriate [transesophageal echocardiogram] views. I digitized the cardiac cycles in the corresponding four chamber and two chamber views in which the mitral regurgitant jet could best be evaluated in the mid portion of systole. The largest representative RJA was 1.1 cm². The LAA was 15.1 cm². Therefore, the largest representative RJA/LAA ratio was 7%, diagnostic of mild mitral regurgitation.

Visually, the left atrium appeared normal in size. I digitized the cardiac cycles in which the left atrium could best be measured. I measured the left atrium with electronic calipers. I determined that the corresponding left atrial antero-posterior diameter in the [transesophageal echocardiogram] was 3.9 cm. The corresponding left atrial measurement in the supero-inferior dimension was 4.9 cm. These measurements were diagnostic of normal left atrial dimensions. These left atrial dimension measurements correspond well with an LAA measurement of 15.1 cm².

As to claimant's December 27, 2001 cardiac catheterization, Dr. Vigilante concluded that "[t]here was no mitral regurgitation seen during sinus beats."

In response to the Technical Advisor Report, claimant asserts that we should disregard the report because the Technical Advisor purportedly did not address or answer any issue relevant to her claim. Specifically, claimant asserts that the Technical Advisor improperly "reviewed, and expressed opinions about, a transesophageal echocardiogram (an echocardiogram not performed

in accordance with the Settlement Agreement criteria) which Claimant had performed on December 27, 2001, i.e., well after the echocardiogram upon which this claim is based." In addition, claimant contends she should receive a refund of the Technical Advisor costs because "[t]he Technical Advisor did not address or determine any issue concerning the echocardiogram of attestation of October 31, 2001."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, claimant does not refute the specific conclusions of the auditing cardiologist or the Technical Advisor that her December 27, 2001 echocardiogram does not reveal the presence of moderate mitral regurgitation or an abnormal left atrial dimension. In particular, Dr. Yao noted that claimant's December 27, 2001 echocardiogram demonstrated only "mild mitral regurgitation" and a "normal" left atrial dimension. Similarly, Dr. Vigilante concluded that Ms. Porter's December 27, 2001 echocardiogram showed "very mild mitral regurgitation" and "normal left atrial dimensions."

Instead, claimant argues that the Trust could not rely on her December 27, 2001 echocardiogram and cardiac catheterization in determining whether there was a reasonable medical basis for her attesting physician's representations of moderate mitral regurgitation and an abnormal left atrial dimension based on the report of her October 31, 2001

echocardiogram. In support of this argument, claimant relies on § VI.C.4.b. of the Settlement Agreement:

If the Class Member seeking a Matrix payment is unable to obtain the [Medical Information] described above through the exercise of reasonable efforts, the Trustees and/or Claims Administrator(s) shall have the right to consider other supporting documentation including but not limited to declarations of other Qualified Physician(s) under penalty of perjury setting forth opinion(s) to a reasonable degree of medical certainty to support the claim that the Class Member's condition entitles him or her to a Matrix payment, subject to review by the Court as set forth in Section VIII.D. If this evidence establishes the Class Member's condition to the satisfaction of the Trustees and/or Claims Administrator(s), the Class Member shall be entitled to receive the appropriate Matrix Compensation Benefits.

Contrary to claimant's argument, nothing in this provision requires the Trust to consider only documents that support payment of a claim. Under the plain text of this provision, the Trust may "consider" other material and a claimant only is entitled to receive "appropriate" Matrix Benefits if the materials establish the necessary medical condition "to the satisfaction of the Trustees and/or Claims Administrator(s)." The claimant is correct in noting that the Settlement Agreement, upon the satisfaction of certain conditions, allows a claimant to rely on the results of an echocardiogram when the echocardiogram itself can no longer be located. See Settlement Agreement §§ VI.C.2.e. and f. However, nothing in the Settlement Agreement requires the Trust simply to accept the findings stated in an

echocardiogram report where the echocardiogram tape is no longer in existence.

Further, claimant's argument ignores § VI.E.6. of the Settlement Agreement, which states:

In conducting an audit of those Claims and Requests for Credit selected for audit, the Trustees and/or Claims Administrator(s) shall follow the following procedure: All Accelerated Implementation Option acceptance form(s) ("PINK FORM"), registration form(s) ("BLUE FORM"), videotapes or disks of Echocardiograms, medical reports, and other information submitted by AHP in support of a Request for Credit or by a Class Member in support of a Claim, together with a copy of the claimant's medical records, and Echocardiogram videotapes or disks obtained by the Trustees/Claims Administrator(s) shall be forwarded to a highly-qualified, independent, Board-Certified Cardiologist (hereinafter referred to as the "Auditing Cardiologist") selected by the Trustees/Claims Administrator(s). After thoroughly reviewing these materials, the Auditing Cardiologist shall make a determination as to whether or not there was a reasonable medical basis for the representations made by any physician in support of the Claim or Request for Credit.

Id. § VI.E.6.; see also Audit Rule 7(a). Accepting claimant's interpretation would effectively negate this provision of the Settlement Agreement.

Finally, claimant's interpretation is not supported by the parties responsible for drafting the Settlement Agreement, namely, Class Counsel and Wyeth. In October, 2010, we requested the views of Wyeth and Class Counsel as to the parties' intention with respect to § VI.C.4.b. and §§ VI.C.2.e. and f. of the Settlement Agreement. See PTO No. 8549 (Oct. 18, 2010). In a

joint response, Class Counsel and Wyeth stated their position as follows:

Where the tape or disk of the Qualifying Echocardiogram, the echocardiogram that supports the presence of a Matrix Level condition and/or the echocardiogram that supports the presence or absence of a Reduction Factor no longer exists or cannot be found, the Class Member must submit a sworn affidavit from the last custodian of the tape or disk documenting that such tape or disk no longer exists and explaining to the satisfaction of the Trust the circumstances under which the tape or disk "came to be misplaced or destroyed."

If the Class Member makes that showing, the Trust may rely upon other medical evidence regarding the presence or absence of the regurgitation diagnosed by the Qualifying Echocardiogram, the presence or absence of a Matrix Level condition, and the presence or absence of a Reduction Factor, including the written [echocardiogram] report of the missing tape or disk prepared when the echocardiogram was conducted and all other Medical Information submitted on the claim, such as hospital records, results of cardiac catheterizations, surgical reports, pathology reports, and any other echocardiogram studies. The Auditing Cardiologist shall weigh all such Medical Information and the totality of the medical facts presented in evaluating whether there is a reasonable medical basis for the level of regurgitation on the Qualifying Echocardiogram, the presence of a Matrix Level condition and the absence of pertinent reduction factors as asserted by the Attesting Physician in the Green Form submitted by the Class Member in support of the Class Member's Matrix claim.

(emphasis added.)

This is precisely what occurred here. The claimant was permitted to proceed with her claim upon submission of the required documentation to establish that her October 31, 2001

echocardiogram was no longer in existence. The Trust was permitted to consider, among other things, claimant's December 27, 2001 echocardiogram and cardiac catheterization in determining whether there was a reasonable medical basis for the attesting physician's representations.¹⁰ As a review of those materials revealed that the attesting physician's representations lacked a reasonable medical basis, the Trust denied claimant's request for Level II Matrix Benefits.

Claimant's reliance on § VI.C.1.d. of the Settlement Agreement is similarly misplaced. This provision of the Settlement Agreement states:

A claimant who qualifies for a particular Matrix payment, by virtue of a properly interpreted Echocardiogram showing the required levels of regurgitation and/or complicating factors, after exposure to fenfluramine and/or dextfenfluramine, shall not be disqualified from receiving that Matrix payment in the event that a subsequent Echocardiogram shows that the required levels of regurgitation and/or complicating factors are no longer present.

Settlement Agreement § VI.C.1.d. Contrary to Ms. Porter's argument, she had not yet "qualifie[d] for a particular Matrix payment." In particular, we disagree with claimant that the report of her October 31, 2001 echocardiogram and the affidavit of her reviewing cardiologist, Dr. Curtis, established a

10. For these reasons as well, we reject claimant's argument that the Technical Advisor Report did not address or answer any question relevant to the issues presented by this claim and her request that she be refunded Technical Advisor costs.

reasonable medical basis for her claim that she was qualified to receive Level II Matrix Benefits under the Settlement Agreement.

We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include failing to review multiple loops and still frames. Mem. in Supp. of PTO No. 2640, at 9-13 (Nov. 14, 2002). We also previously have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of regurgitation are representative of the level of regurgitation throughout an echocardiogram." Mem. in Supp. of PTO No. 8659, at 10 (Aug. 8, 2011) (quoting Mem. in Supp. of PTO No. 6997, at 11 (Feb. 26, 2007)); see also In re: Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). "'To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.'" Memo. in Supp. of PTO No. 8659, at 10. Indeed, nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition.

Here, Ms. Porter failed to provide any evidence that the "eccentric laterally directional jet of mitral insufficiency" identified on the echocardiogram report for her October 31, 2001 echocardiogram was representative of moderate mitral regurgitation that could be observed throughout her echocardiogram. Although claimant submitted an affidavit from the reviewing cardiologist for this echocardiogram, the affidavit merely incorporated by reference the text of the echocardiogram report without any additional analysis. Dr. Curtis never stated that claimant's October 31, 2001 echocardiogram revealed the specific level of moderate regurgitation required by the Settlement Agreement. See Settlement Agreement § I.22. In fact, he specifically stated that claimant's October 31, 2001 echocardiogram was conducted and reviewed in the course of regular treatment, not interpreted pursuant to the requirements of the Settlement Agreement.¹¹ In contrast, Dr. Vigilante stated in his report that he reviewed claimant's record "in accordance with the standards set forth in the Green Form and in the Nationwide Class Action Settlement Agreement with American Home Products Corporation." On this basis as well, claimant failed to establish a reasonable medical basis for her attesting physician's representation that she had moderate mitral regurgitation. As such, the Trust did not, as claimant contends,

11. For this reason as well, we reject claimant's assertion that Dr. Curtis was in the best position to determine the level of claimant's mitral regurgitation.

violate § VI.C.1.d. of the Settlement Agreement by considering claimant's December 27, 2001 echocardiogram.¹²

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation and an abnormal left atrial dimension. Therefore, we will affirm the Trust's denial of Ms. Porter's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

12. We also reject claimant's argument that neither the Trust nor the Technical Advisor could consider claimant's transesophageal echocardiogram. We have previously noted that a transesophageal echocardiogram may be used in certain circumstances to determine whether there is a reasonable medical basis for a claim. See, e.g., PTO No. 7492, at 9 n.11 (Nov. 5, 2007). Significantly, claimant does not contest that her December 27, 2001 transesophageal echocardiogram fails to show moderate mitral regurgitation as defined under the Settlement Agreement.